

Avian Flu: Addressing the Global Threat

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Chairman Hyde, Congressman Lantos and other distinguished members of the Committee on International Relations, I'm honored to appear before you this morning to discuss the critical threat of pandemic influenza and the implications of the global, just-in-time economy on our nation's ability to respond to and during a pandemic.

First, while there has been wide-spread attention paid to the possibility that the H5N1 influenza virus (or avian influenza) may be the cause of the next pandemic, I believe that there is confusion with regard to the likelihood that an H5N1 pandemic will occur. Congress has heard over recent months from a number of informed witnesses that we must be much better prepared to respond to the threat of an H5N1 pandemic.

I want to clarify one point with regard to the eventuality of such a pandemic. We must never forget that influenza pandemics are like earthquakes, hurricanes and tsunamis; they occur. Dating back to antiquity, influenza pandemics have posed the greatest threat of a world-wide calamity caused by infectious disease. Over the past 300 years, ten influenza pandemics have occurred among humans. The most recent came in 1957-58 and 1968-69 and although several tens of thousands of Americans died in each one, these were considered mild compared to others. The 1918-19 pandemic was not. According to a recent analysis it killed 50-100 million people globally. Today with a population of 6.5 billion, more than three times that of 1918, even a mild pandemic could kill many millions of people.

A number of recent events and factors have heightened our concern that a specific near-term pandemic may be imminent. It could be caused by the H5N1 strain currently circulating in Asia and parts of Europe. At this juncture, we as scientists cannot be certain. Unfortunately there are many ominous signs that make this risk something that only a fool would dismiss. We cannot know exactly when a pandemic will hit or whether it will rival the experience of 1918-19 or be more muted like 1957-58 and 1968-69. The reality of a coming pandemic however, cannot be avoided, only its impact can be lessened. Some important preparatory efforts are underway, but much more needs to be done by institutions at many levels of society throughout the world.

I firmly believe that based on our past experiences with outbreaks such as SARS and even the post-9/11 anthrax attack, that if an influenza pandemic began today, borders will close, the global economy will shut down, pharmaceutical supplies, including drugs and very important childhood vaccines will be in extreme short supply, healthcare systems will be overwhelmed and panic will reign. Access to pandemic influenza vaccines and effective antiviral drug treatments will be limited for the entire world for years to come because of our lack of modern technology vaccines and a grossly inadequate worldwide production capability. To minimize the fallout of a pandemic during this time, the industrialized world must create a detailed response strategy far beyond just enhancing influenza vaccines and treatment drugs, and one that involves both the public and private sectors. In addition, we can no longer assume that business continuity plans for both our multinational companies and small businesses, largely based on a concept of a regional event of a limited duration, will approximate the actual

impact and consequence of an influenza pandemic. Rather, I believe an influenza pandemic will be like a 12 to 18 month global blizzard that will ultimately change the world as we know it today. This will occur even if we experience a milder worldwide pandemic of millions of deaths rather than many millions of deaths.

I have detailed the basic steps necessary for preparing for the next pandemic whether it begins tonight, next year, or even ten years from now in an article in the July-August issue of *Foreign Affairs*. That article has been provided to you for reference. I will attempt not to repeat the points covered in that article, but rather reflect on a single critical area that I believe continues to be largely neglected by governments throughout the world and by many of our leading private- sector companies.

The arrival of an influenza pandemic will trigger a reaction that will change the world overnight. Foreign trade and travel will be reduced or even ended in an attempt to stop the virus from entering new countries – even though such efforts will probably fail given the infectiousness of influenza and the volume of illegal crossings that occur at most borders. It is likely that transportation will also be significantly curtailed domestically, as states and communities seek to keep the disease contained. Our modern world has come to rely on the speedy, “overnight” distribution and delivery of many products including medical supplies, our food and replacement parts for essential infrastructure-related equipment. With an influenza pandemic, global, regional, and national economies will come to an abrupt halt – something that has never happened due to HIV, malaria, or TB despite their dramatic impact on the developing world.

One part of pandemic preparedness planning that must receive immediate attention is the implementation of a concept that I have called “critical product continuity” (CPC). “Critical product continuity is the determination of those products and services that our country routinely enjoys that must be available during a pandemic in order to minimize potentially catastrophic collateral health and security consequences and the subsequent comprehensive actions that must be taken by both governments and the private sector to ensure their availability.” For example, in the health care delivery system, regardless of where routine and influenza-related patient care takes place, we will need even more of our routine drugs and vaccines, medical devices and other products such as needles, syringes, IV bags, gloves, masks and routine diagnostic materials such as standard laboratory and diagnostic tests. Most of these products have supply chains and production locations that are primarily outside of the United States. Other critical product categories include both domestic and foreign suppliers of our food supply and for essential parts for the maintenance of critical infrastructures such as our water supplies, electricity and vital communications. We must also ensure a source of heating during the winter months for our northern climates; gasoline for critical domestic and international transportation; routine waste management and sanitation; and even corpse management. It is difficult to imagine how discretionary items such as non-vital electronics, jewelry, automobiles and entertainment will be needed during this time to ensure our health and safety. While any negative impact to our economy will be unfortunate, we must make difficult strategic decisions about which products and services our government, together with selected private sector companies, must

maintain through critical supply chain support, the maintenance of adequate workforces and necessary transportation assurance whether domestic or abroad.

Let me provide you with one example of a critical product continuity that if not addressed now will result in dramatic collateral damage to our country during the 12 to 18 months of an influenza pandemic. Today, millions of Americans count on routine prescription drugs and over-the-counter pharmaceutical supplies to treat a variety of life-threatening, chronic or routine illnesses. As part of the global just-in-time economy world that we live in, the pharmaceutical industry has responded to investor demands for greater efficiency and thus higher investment return. In order to achieve greater productivity within this industry, both inventory management or just-in-time delivery, and identifying cheaper production environments with limited supply chain costs, have resulted in an extremely vulnerable pharmaceutical industry environment for sustaining ongoing production during events such as a pandemic. For example, more than 80 percent of the raw materials used in the production of pharmaceutical products available in this country come from outside the United States. Any interruption of trade and transportation of multiple regions of the world will result in numerous pharmaceutical products not being available in this country or at the minimum; they will be in very short supply. In addition, inventory management often contributes to potential drug shortages. Common business practice today dictates a “just-in-time” inventory system. Manufacturers generally stock a 30-day supply of raw materials and products, distributors will often have a 30-45 day supply in hand and most pharmacies average 10-16 inventory turnovers per year. While this practice makes inventory control sense,

a small glitch in supply or production can become a major supply problem resulting in drug shortages. Today, even with a pharmaceutical production system absent of any major international calamities that disrupt production and transportation, the American Society of Health-System Pharmacists has determined that 49 drugs or vaccine products in the United States are currently unavailable, in short supply or at risk of short supply due to manufacturing, inventory or supply chain issues. These products include routinely used antibiotics, cancer and cardiac drugs and a variety of other standard treatments. Unfortunately, even consumers with health insurance or government-supported pharmaceutical drug benefits can not anticipate a potential pandemic by stockpiling a several month supply of essential drugs because most benefit requirements do not allow the purchase of more than one month supply of drug. Imagine this country during a pandemic, when most of the routine pharmaceutical products that we count on every day are likely no longer available. Add that to the dramatic impact of pandemic influenza and an already terrible situation becomes even worse. Given the very large proportion of raw materials used in pharmaceutical products that come from outside the United States, this issue should be a major concern of this Committee and others involved with our international relations and trade considerations. We must understand the implications and plan for the shutdown of our global economy and supply chains now; not during a pandemic.

While I have chosen to highlight the issue of critical product continuity and the pharmaceutical industry, it is important that the committee remember that there are many other product areas as noted above that must be considered as we plan for

getting through “the next 12 to 18 month pandemic”. I am unaware of any government or private sector effort to identify and respond in a comprehensive manner to this critical product continuity issue. I have been fortunate in recent weeks to work with former Health and Human Services Secretary Tommy G. Thompson, now part of the Akin, Gump, Strauss Hauer and Feld law firm here in Washington, DC, to identify ways to empower and assist the private sector in responding to this critical product continuity issue. However, in the first instance our federal government must understand that it will take an effort with the similar commitment of resources, vision and management as we are putting forward for influenza vaccine and drug research, procurement and distribution if we are to minimize the serious collateral damage that will occur to our society as a result of critical product and services shortages during the next pandemic. It is my hope that this Committee will recognize this important international and domestic issue and provide the leadership in Congress to rapidly address it.

Thank you.